Federal Court Cour fédérale

Date: 20230808

Docket: T-651-23

Citation: 2023 FC 1075

Ottawa, Ontario, August 8, 2023

PRESENT: The Honourable Madam Justice Strickland

BETWEEN:

ORGANIGRAM INC

Applicant

and

ATTORNEY GENERAL OF CANADA

Respondents

JUDGMENT AND REASONS

[1] This is the judicial review of a decision of Health Canada, Compliance Directorate, Controlled Substances and Cannabis Branch [Health Canada] made on behalf of the Minister of Health [Minister], dated March 1, 2023, determining that Edison Jolts [Jolts], a product manufactured by the Applicant, Organigram Inc. [Organigram], are to be classified as edible cannabis. As such, the Minister found that the Jolts contain a quantity of delta-9-tetrahydrocannabinol [THC] that exceeds the allowable limit of 10 mg per immediate container for that product classification, in contravention of s 102.7 of the *Cannabis Regulations*,

SOR/2018-144 [*Cannabis Regulations*]. The application is brought pursuant to s 18.1 of the *Federal Courts Act*, RSC 1985, c F-7.

[2] Ultimately, the issue in this matter is Health Canada's decision to classify the Jolts, which are in "lozenge" form, as edible cannabis rather than cannabis extract, the latter having a higher permissible amount of THC per package (1000 mg per immediate container).

Legislative Background

[3] It is helpful to first provide the legislative backdrop to this matter to provide context for the parties' positions and analysis that follows.

[4] The production, distribution and sale of cannabis products in Canada is governed by the *Cannabis Act*, SC 2018 c 16 [*Cannabis Act* or *Act*] and the *Cannabis Regulations*. By Order dated December 11, 2019, the Governor in Council, pursuant to section 4 of the *Act*, designated the Minister of Health as the Minister for the purpose of the *Act*, thereby granting authority to Health Canada as the regulator of such products.

[5] The *Cannabis Act* describes its purpose as follows:

> **Purpose**
>
> **7** The purpose of this Act is to protect public health and public safety and, in particular, to
>
> > **(a)** protect the health of young persons by restricting their access to cannabis;
> >
> > **(b)** protect young persons and others from inducements to use cannabis;

> **(c)** provide for the licit production of cannabis to reduce illicit activities in relation to cannabis;
>
> **(d)** deter illicit activities in relation to cannabis through appropriate sanctions and enforcement measures;
>
> **(e)** reduce the burden on the criminal justice system in relation to cannabis;
>
> **(f)** provide access to a quality-controlled supply of cannabis; and
>
> **(g)** enhance public awareness of the health risks associated with cannabis use.

[6] The *Cannabis Regulations* describe the seven classes of cannabis products that may be sold in Canada (*Cannabis Act*, s 33 and Schedule 4). These include cannabis extract and edible cannabis, which are defined in s 1(1) as follows:

> ***cannabis extract*** means
>
> **(a)** a substance produced by
>
> **(i)** subjecting anything referred to in item 1 of Schedule 1 to the Act to extraction processing, or
>
> **(ii)** synthesizing a substance that is identical to a phytocannabinoid produced by, or found in, a cannabis plant; or
>
> **(b)** a substance or mixture of substances that contains or has on it a substance produced in a manner referred to in paragraph (a).
>
> It does not include a cannabis topical or edible cannabis.
>
> ***edible cannabis*** means a substance or mixture of substances that contains or has on it anything referred to in item 1 or 3 of Schedule 1 to the Act and that is intended to be consumed in the same manner as food. It does not include dried cannabis, fresh cannabis, cannabis plants or cannabis plant seeds.
>
> ***food*** has the same meaning as in section 2 of the *Food and Drugs Act*

[7] The *Cannabis Regulations*, among other things, concern the regulation of cannabis products (Part 6), cannabis promotion (Part 6.1) and cannabis packaging and labelling (Part 7).

[8] Part 6 includes provisions that prescribe the maximum quantity of THC that may be contained in in a product of a certain class, as well was what other ingredients are permitted to be used in that product:

> **PART 6**
>
> **Cannabis Products**
> General Provisions
>
> **Maximum quantity of THC — discrete unit**
>
> **96 (1)** Subject to subsection 97(1), each discrete unit of a cannabis product that is intended for ingestion or nasal, rectal or vaginal use must not contain a quantity of THC that exceeds 10 mg, taking into account the potential to convert THCA into THC.
>
> **Exception**
>
> **(2)** Subsection (1) does not apply to edible cannabis.
>
> **Cannabis Extracts and Cannabis Topicals**
> **Maximum quantity of THC**
>
> **101.2** A cannabis extract, or a cannabis topical, that is a cannabis product — or that is contained in a cannabis accessory that is a cannabis product — must not contain a quantity of THC that exceeds 1000 mg per immediate container, taking into account the potential to convert THCA into THC
>
> **Cannabis extract — content**
>
> **101.3 (1)** A cannabis extract that is a cannabis product — or that is contained in a cannabis accessory that is a cannabis product — must not contain any ingredients other than
>
> **(a)** carrier substances;
>
> **(b)** flavouring agents; and

(c) substances that are necessary to maintain the quality or stability of the cannabis product.

Prohibited ingredients

(2) The following substances must not be used as ingredients to produce a cannabis extract referred to in subsection (1):

(a) substances that are listed in column 1 of the table in Schedule 2 to the *Tobacco and Vaping Products Act*; or

(b) sugars or *sweeteners* or *sweetening agents*, as those terms are defined in subsection B.01.001(1) of the *Food and Drug Regulations*.

…….

Edible Cannabis
Ingredients — edible cannabis

102 (1) Edible cannabis that is a cannabis product — or that is contained in a cannabis accessory that is a cannabis product — must not contain any ingredients other than food and food additives.

….

Food additives

(5) A holder of a licence for processing may use a food additive as an ingredient to produce edible cannabis referred to in subsection (1) only if

(a) the edible cannabis would be a food that is the subject of a marketing authorization if the edible cannabis did not contain or have on it anything referred to in item 1 or 3 of Schedule 1 to the Act;

(b) the marketing authorization permits the food additive to be in or on the food;

(c) the conditions under which the marketing authorization permits the food additive to be in or on the food — including any maximum levels of use — are complied with; and

(d) the food additive is not caffeine or caffeine citrate.

> **Maximum quantity of THC**
>
> **102.7** Subject to subsection 97(2), edible cannabis that is a cannabis product — or that is contained in a cannabis accessory that is a cannabis product — must not contain a quantity of THC that exceeds 10 mg per immediate container, taking into account the potential to convert THCA into THC.

[9] Thus, edible cannabis has a THC limit of 10 mg per immediate container while cannabis extract has a considerably higher limit of 1000 mg per immediate container.

[10] Part 12 of the *Cannabis Regulations*, Reporting and Disclosure, includes the requirement that a processing licence holder must, at least 60 days before making a new cannabis product available for sale, provide the Minister with written notice containing the prescribed information:

> **Notice — new cannabis product**
>
> **244 (1)** A holder of a licence for processing, at least 60 days before making available for sale a cannabis product — except cannabis plants or cannabis plant seeds — that they have not previously sold in Canada, must provide the Minister with a written notice that contains the following information:
>
> > **(a)** the class of cannabis set out in Schedule 4 to the Act to which the cannabis product belongs;
> >
> > **(b)** a description of the cannabis product, including the brand name; and
> >
> > **(c)** the date on which the cannabis product is expected to be made available for sale.

[11] There does not appear to have been a published policy or procedure to be followed by Health Canada upon receipt of a s 244(1) notice, known as a notice of new cannabis product [NNCP]. Based on the procedure followed in the record before me, it appears that upon review

of a NNCP, if Health Canada is of the view that the product information presented is potentially in contravention of the *Cannabis Act* or *Cannabis Regulations*, then it may advise the producer of its concerns by way of a letter, referred to as a compliance promotion letter, and request the producer to respond.

[12] In the event that Health Canada subsequently identifies an issue of non-compliance, then it may issue a notice of non-compliance to the producer setting out Health Canada's concerns and identifying any actions required, such as the voluntary stop sale of the product at issue.

[13] Health Canada will then make a final determination as to compliance.

Factual Background

[14] Organigram is a licensed producer of cannabis and cannabis products in Canada.

[15] On December 4, 2020, Health Canada wrote to Organigram to inform it that the information provided in the NNCPs submitted with respect to the Jolts' precursor products suggested that activities in connection with the products could potentially contravene the *Cannabis Act* and/or the *Cannabis Regulations*. Specifically, the NNCPs classified the products as "cannabis extract" with the ingredient oligofructose. Health Canada noted that s 101.3(2) of the *Cannabis Regulations* indicates that identified substances must not be used as ingredients to produce a cannabis extract referred to in s 101.3(1), including "sugars or sweeteners or sweetening agents, as those terms are defined in subsection B.01.001(1) of the *Food and Drug Regulations*".

[16] Health Canada noted that the definition of sweetener in Part B, division 1, s B.01.001(1) of the *Food and Drug Regulations,* CRC, c 870 ultimately refers to the *List of Permitted Sweeteners* published on the Health Canada website, which includes sorbitol as a sweetener. Health Canada requested a response to its concern within two days.

[17] Organigram responded on the same date indicating that oligofructose is a family of chemical compounds that are distinct from sorbitol and that oligofructose does not appear on the *List of Permitted Sweeteners* and is instead classified by Health Canada as a dietary fibre on its *List of Dietary Fibres Reviewed and Accepted by Health Canada's Food Directorate*. Organigram stated that oligofructose's role in the product is to serve as a bulking agent and carrier for the cannabis present in the product.

[18] By email dated February 8, 2021, Health Canada addressed Organigram's response and, among other things, stated that Organigram had received the December 4, 2020 compliance promotion letter because Health Canada had performed a preliminary assessment of the subject NNCPs. With respect to sorbitol being mentioned in the letter, this was in error and the letter should have said oligofructose. In relation to the ingredient oligofructose, Health Canada stated that sugars, sweeteners or sweetening agents are prohibited as ingredients for cannabis extract to prevent inducements to use cannabis, and in particular, to help reduce the appeal of these products to young persons. Further, Health Canada noted that there is no exemption provided in the *Cannabis Regulations* for other functions. Regardless of the intent of its use, the ingredient oligofructose could impart a sweet taste and therefore may be in contravention of s 101.3(2)(b) of the *Cannabis Regulations*. Health Canada again pointed out that s 101.3(2)(b) precludes the

use of sugars or sweeteners or sweetening agents, and that the definition of sweeteners as referred to in subsection B.01.001(1) of the *Food and Drug Regulations* is "a food additive that is used to impart a sweet taste to a food". Health Canada stated that since oligofructose can be used to impart a sweet taste, and since there is no exemption in the *Cannabis Regulations* for the use of sweeteners as other functions other than what is defined, the use of oligofructose may not comply with s 101.3(2)(b).

[19] A telephone discussion was held on February 16, 2021, and Organigram responded to Health Canada's February 8, 2021 email by letter of February 19, 2021. Organigram advised that the final product it intended to launch had been developed, which it described, and that a new NNCP would be submitted (the Jolts). Organigram took the position that oligofructose is not a prohibited sweetener under s 101.3(2) on the basis that the *List of Permitted Sweeteners* published by Health Canada that is ultimately referred to in the definition of sweetener in s B.01.001(1) of the *Food and Drug Regulations* does not include oligofructose. Organigram also submitted that lozenges containing oligofructose are consistent with Health Canada's policy goal of prohibiting sweeteners in cannabis products to help reduce the appeal of those products to young people.

[20] On March 1, 2021, Health Canada sent an email to Organigram advising that it acknowledged Organigram's rational provided for the use of oligofructose in its (precursor) products and had attached the rational to the NNCPs affected.

[21] Organigram subsequently submitted NNCPs for each flavour of the Jolts: the NNCP for Freshly Minted Sativa flavour was submitted on April 6, 2021, Electric Lemon on November 17, 2021 and Arctic Cherry on December 1, 2021. The submissions indicated that the Jolts are in the cannabis extract class, the intended use is by ingestion, the product is in lozenge form, and there is 10 mg of THC per unit (lozenge). The ingredients were listed as oligofructose, glycerine, water, soy lecithin, sulphates and flavouring agent. The sensory attributes of the product (flavour, scent, colour, shape) were described as menthol flavour and scent, pale yellow in colour and round in shape.

[22] The first Jolts product launched in August 2021.

[23] On January 14, 2022, Health Canada sent Organigram a compliance promotion letter pertaining to the NNCPs for the three Jolts products. Its stated purpose was to inform Organigram that information presented in the NNCPs suggested that activities in connection with the products could potentially contravene the *Cannabis Act* or *Cannabis Regulations*. Specifically, as submitted in the Cannabis Tracking and Licensing System, the products were classified as “Cannabis extract” in the form of “lozenge” and had the appearance of round candies. Health Canada stated that, for the purpose of determining the appropriate class of cannabis, examining if the products would be considered as a food, should they not contain cannabis, constituted a relevant exercise. If the products in question were to be considered food, they would most likely fit the definition of edible cannabis in the *Cannabis Regulations* because they would be “intended to be consumed in the same manner as food”. Health Canada referred to the definition of “food” in the *Food and Drugs Act*, RSC 1985, c F-27 and its *Guidance*

Document: Classification of products at the food-natural health product interface: products in food formats [*Guidance Document*], which sets out criteria to assess if a product should be considered a food. Health Canada concluded, in light of the *Food and Drug Act* definition of "food", the criteria included in the *Guidance Document* such as product format, product composition, product representation and public perception and, the definition of edible cannabis in the *Cannabis Regulations,* that the Jolts were believed to be consumed in the same manner as food. Therefore, they fit the definition of edible cannabis as established by the *Cannabis Regulations,* and such classification would result in potential non-compliance with s 123(1)(b) and s 102.7 of the *Cannabis Regulations*. Health Canada sought a response from Organigram within five days.

[24] Organigram responded by letter of January 21, 2022. It took the position that the Jolts products do not meet the definition of "food" as found in the *Food and Drugs Act* because the products are not represented for use as food. Instead, they are slow acting sublingual lozenges. Organigram stated that because the products do not meet that definition, and are not intended to be consumed in the same manner as food, they would not be properly classified as cannabis edibles. Organigram also submitted that the products are not properly classified as food in accordance with the *Guidance Document* and set out its reasoning for this view.

[25] By email of March 4, 2021, Health Canada advised that it had conducted a preliminary assessment of the information contained in the subject NNCPs and sought clarification as to the percentage composition of the ingredient oligofructose and its function. Organigram responded on March 11, 2022, advising that the percentage composition of oligofructose was 93.2 - 97.5%,

and glucose+fructose+sucrose was 2.5 - 6.8%. Organigram stated that oligofructose is a bulking agent and carrier and that carriers are permitted pursuant to s 101.3(1)(a) of the *Cannabis Regulations*.

[26] By email of March 17, 2022, Health Canada acknowledged receipt of Organigram's January 21, 2022 response and advised that it had no further questions at that time.

[27] On September 22, 2022, Health Canada again advised that it had performed a preliminary assessment of the information contained in the identified NNCPs, which included the Jolts, and sought clarification as to the constituents of the ingredient "sulphites" and the role of the ingredient "oligofrutose". On September 29, 2022, Organigram responded, stating that the sulphites are used as a processing aid in the manufacture of the bulking agent and carrier, oligofrutose. And, as previously advised in connection with other Jolts products, that oligofructose is a bulking agent and carrier.

[28] On October 17, 2022, Health Canada received a complaint letter [Complaint]. This letter advocated to increase the 10 mg THC limit for edible cannabis but, until that was done, asserted that Health Canada should take steps to preserve the integrity of the distinction between cannabis extract and edible cannabis. The letter attached marketing materials of various products, including the Jolts, and requested that they be scrutinized as they positioned themselves as cannabis extract products but otherwise appeared to be intended to be consumed in the same manner as food.

[29] Following the Complaint, Health Canada's Compliance Risk Management Unit conducted a preliminary classification [Preliminary Classification] of the Jolts, which classification is indicated to be based on an internal *Policy on the Classification of Ingestible Extracts* [*Classification Policy*]. This classification considered product representation, format and public perception, and assessed that the products would be better classed as edible cannabis.

[30] On January 3, 2023, Health Canada wrote to Organigram stating that the purpose of the letter was to inform Organigram that Health Canada had identified non-compliance with s 102.7 of the *Cannabis Regulations* with respect to the Jolts line of cannabis products [Notice of Non-Compliance]. Health Canada stated that upon further review of the products the Jolts were assessed as edible cannabis and, consequently, that they contain a quantity of THC that exceeds the allowable limit if 10 mg per immediate container. Health Canada set out its reasoning for this finding, including the definitions of edible cannabis, cannabis extract and food in the *Cannabis Regulations.* Health Canada stated, based on those definitions, that the *Cannabis Regulations* provide that an ingestible cannabis product that meets the definition of edible cannabis, especially a product that is intended to be consumed in the same manner as food, is edible cannabis and cannot be classified as a cannabis extract. Health Canada stated that it had determined that the Jolts are consumed in the same manner as food and, therefore, fit the definition of edible cannabis. Its assessment of the products was based on product representation, product format, and public perception or history of use, and found:

1) The products have a likeness to confectionary-like products. The directions on the packages indicate that they are "Cannabis extract (lozenge) for ingestion".

2) The products are represented and marketed in a manner that highlights their taste and flavour. Cherry, lemon and mint are food flavours that are generally associated with confectionary products, or desserts.

3) Organigram Edison Jolts cannabis extract product line may be perceived by consumers as intended for consumption in the same manner as both food products and cannabis edibles. Confectionary products have a long history of being consumed as foods. This position is consistent with the *Guidance* for classifying food and natural health products.

[31] Health Canada requested that Organigram voluntarily stop the sale of the Jolts cannabis extract products and to submit a response within five days.

[32] On January 6, 2023, Organigram provided its response to the Notice of Non-Compliance. Its position was that the Jolts products do not meet the definition of "food" and are not properly classified as a food in accordance with the *Guidance Document*. Organigram set out its reasoning in that regard which included that:

- The Jolts are not represented for use as food, as they are slow dissolving sublingual lozenges and users are advised to suck the lozenges until the flavour peaks (about 15 seconds), then hold them under their tongue or between cheek and gum until fully dissolved. This is in contrast to food which is typically chewed then swallowed. Nor is the product particularly palatable. Their format, a harsh menthol flavour and other attributes, illustrate that the products are not intended to be consumed as foods and are not perceived as such by consumers;

- as to product composition, in contrast to candies, the Jolts do not contain any sugar, sweetener or other sweetening agents as would be contained in a confectionary product. The mint, lemon and cherry flavours are not exclusively associated with foods, and the ingredients are not present for any food-like reasons, but for functional effect;

- as to product representation and format, the Jolts products are labelled with directions that are inconsistent with the consumption of food, their packaging does not represent them as confectionary products, such as candy or sweets, nor are their flavours highlighted. They are not presented for ad libitum use and their long lasting lozenge format and inclusion of a harsh menthol flavor guards against this; and

- as to public perception and history of use, there is significant evidence of historical use of lozenges falling outside the food category and the public perceives lozenges to be something other than food.

[33] Organigram also advised that it did not intend to take any stop sale action and requested that Health Canada advise of its availability for a discussion.

[34] During a requested telephone discussion held with Health Canada on January 13, 2023, Organigram again explained why, in its view, the Jolts were compliant with the *Cannabis Regulations.* At that time, Health Canada confirmed that a written response would follow.

[35] A second classification process for the Jolts products [Second Classification] was started on January 13, 2023, which considered a number of factors (product representation, sensory and physical characteristics, format, and history of use), as well as Organigram's submissions identified by Health Canada as responding to each of these factors. The Second Classification recommended to maintain the Preliminary Classification of the Jolts as edible cannabis. It found that the descriptor "lozenge" and its associated history of use did not appear sufficient to counterbalance the other factors, and that the cannabis lozenges did not appear very different from cannabis drops or cannabis hard candies.

[36] On March 1, 2023, Health Canada advised Organigram of its decision that the Jolts are properly classified as edible cannabis products. That decision is the subject of this judicial review.

[37] A motion brought by Organigram, seeking an interim order staying the decision until this application of judicial review had been finally disposed of, was dismissed by Order of this Court dated June 1, 2023.

Decision Under Review

[38] In its decision sent by letter entitled Non-Compliance Determination for Edison Jolts, Health Canada referred to its January 3, 2023 Notice of Non-Compliance which informed Organigram of the non-compliance identified pursuant to s 102.7 of the *Cannabis Regulations* with respect to the Edison Jolts Arctic Cherry Lozenges, Electric Lemon Lozenges, and Freshly

Minted Sativa Lozenges. It also acknowledged Organigram's January 6, 2023 written response and information provided during the January 13, 2023 conference call.

[39] The stated purpose of the decision letter was to confirm Health Canada's view that the Jolts, in the form they were being sold on January 3, 2023, are edible cannabis. Health Canada set out a summary of why the Jolts meet the definition of edible cannabis and determined, therefore, given their THC content of 100 mg per immediate container, that they exceed the 10 mg limit stipulated by s 102.7 of the *Cannabis Regulations.*

[40] The explanation included the definitions of edible cannabis and cannabis extract. Health Canada stated that the definition of cannabis extract specifically mentions that it does not include edible cannabis. Cannabis products intended to be consumed in the same manner as food are edible cannabis and therefore excluded from the definition of cannabis extract.

[41] The letter then states:

> In the notice issued to you on January 3, 2023, Health Canada provided Organigram Inc. with an assessment of the Edison Jolts lozenges, including the factors that were considered in assessing the products. Health Canada views these products as being intended for consumption in the same manner as food and therefore they meet the definition of edible cannabis. After considering all the available information, including the submissions and information from Organigram Inc., we are of the view that Edison Jolts are edible cannabis for the following reasons:
>
> *Product format*
>
> The Editon [*sic*] Jolts format is consistent with hard candies, which are confectionary products and a conventional food format according to the relevant portions relating to food in the Guidance Document: Classification of products at the food-natural health

product interface: products in food formats. In addition, the Codex Alimentarius General Standard for Food Additives includes lozenges under the confectionary food category as a hard candy as outlined in the category 05.2.1.We also acknowledge your position that lozenges are commonly regulated as natural health products and not food. However, that classification is dependent on the representation and composition of those products, and not because they are not in a food format. For example, lozenges that are marketed to soothe sore throats (e.g. Halls) are sold as natural health products, as they contain active ingredients and make health claims. A lozenge without any active ingredients nor health claims would be regulated as a hard candy. This is supported by the Canadian Food Inspection Agency's guide "Labelling requirements for confectionary, chocolate and snack food products" which states that the word "lozenge" is an acceptable common name for confectionary products in the absence of any medicinal or therapeutic claims.

Finally, we also acknowledge that lozenges are not generally chewed or swallowed. Food is not required to be chewed, sipped, or swallowed. Chewing gum, which is explicitly listed in the *Food and Drugs Act* s definition of food, is not swallowed, and hard candies are neither intended to be chewed or swallowed.

History of use

As discussed previously, Edison Jolts lozenges are in the format of confectionary products, and more specifically, the format of hard candies. As per the Guidance Document: Classification of products at the food-natural health product interface: products in food formats, it is Health Canada's position that Canadians perceive and consume confectionery products as foods. Confectionery products have a long history of being consumed as foods.

The use of the term lozenge does not automatically result in a classification as a natural health product, as multiple elements must be considered. As explained, natural health products or drugs in the format of lozenges (hard candies) would be regulated as food if they did not contain any active ingredients or have any health claims.

Product sensory and physical characteristics

The Edison Jolts physically resemble hard candies and are sweet tasting with fruity or food-like flavours, including mint, cherry and

lemon. These are sensory and physical characteristics that the public would perceive as or associate with food.

The products appear to be a pale translucent yellow in colour and are spherical in shape. Their appearance does not have any distinguishing features from ordinary hard candies.

The products also use oligofructose and glycerin as primary ingredients. Oligofructose and glycerin are sweet-tasting. They are about 30-50% and 50-75% as sweet as table sugar, respectively. We acknowledge Organigram's position that these ingredients are there for functional purposes only and not intended to satisfy a desire for flavour or taste. However, as a sensory characteristic, the Edison Jolts are sweet tasting, which could lead the public to perceive the products in a similar way to a food product, such as hard candy.

Finally, we acknowledge Organigram's explanation that the flavours are "harsh menthol flavours". However, this does not mean that these flavours were not added to satisfy a desire for taste or flavour. Health Canada is not aware of any functional role of cherry, lemon, and mint flavours other than their use as flavouring agents in the amounts present in the Jolts. We recognize that these flavours are not used exclusively in foods; however, they are flavours of fruits and of food at their base. Their addition increases the likelihood that the public will perceive or associate the Edison Jolts to satisfy a desire for taste or flavour, which is primarily a food purpose.

Product representation

The Edison Jolts are represented and marketed in a manner that associates their taste and flavour with food and a food purpose. The following representations have been used to market the products:

- "A cool blast of arctic cherry flavour"

- "Canada's first 10 mg THC lozenge is now available in an electrifying lemon flavour"

- "These slow-dissolving sublingual lozenges are made without animal products and low in calories"

- "These lozenges are slow dissolving and deliver a jolt of mint flavour"

> These descriptors increase the likelihood that the public would perceive the Edison Jolts as being intended not only to deliver cannabis, but also to satisfy a desire for taste or flavour, which is a food purpose. Their association with food is further reinforced by the descriptor for that they are "low in calories."
>
> We do note that the product comes with specific directions for use:
>
> > - Label instructions: For optimal buccal/sublingual absorption, see EdisonCannabis.Co/extract /jolts. Dissolve slowly.
> >
> > - Online instructions: For optimal sublingual/buccal absorption, suck on lozenge for about 15 seconds, then hold under tongue or between cheek and gum until fully dissolved.
>
> Lozenges are not commonly consumed by keeping them under the tongue. In addition, the Edison Jolts size and shape are not typical to rest comfortably in those cavities compared to sublingual format (for example, sublingual drug or natural health product tablets). This may cause individuals to not follow the instructions provided.
>
> Based on the way the products are represented, a consumer would likely perceive that the Edison Jolts lozenges are intended for a food purpose and to be consumed in the same manner as food.
>
> **Conclusion**
>
> After having considered your representations of January 6 and 13, 2023, and all the information made available to us, we conclude based on the above factors in totality, that the Edison Jolts, as they were sold on January 3, 2023, are edible cannabis. Consequently, they contain a quantity of THC that exceeds the allowable limit of 10 mg per immediate container for that class, which is in contravention of section 102.7 of the *Cannabis Regulations*.

[42] Based on its consideration of the information provided, Health Canada modified its prior request for an immediate stop sale to a phase-out of the Jolts, requiring Organigram to: cease production of new lots of the Jolts in their current format by March 7, 2023; cease the sale and distribution of any remaining inventory of the Jolts in their current format no later than May 31,

2023, and; submit a written response within five business days of the receipt of the decision to confirm actions being taken to address these required actions.

Issues and Standard of Review

[43] Organigram raises two issues:

i. Was the decision reasonable; and

ii. Was the decision made in breach of the duty of procedural fairness?

[44] When a court reviews the merits of administrative decision there is a presumption that the standard of review is reasonableness (*Canada (Minister of Citizenship and Immigrations) v Vavilov*, 2019 SCC 65 at paras 23, 25 [*Vavilov*]. The parties submit, and I agree, that reasonableness is the standard of review applicable to the merits of Health Canada's decision.

[45] "A reviewing court must develop an understanding of the decision maker's reasoning process in order to determine whether the decision as a whole is reasonable. To make this determination, the reviewing court asks whether the decision bears the hallmarks of reasonableness – justification, transparency and intelligibility – and whether it is justified in relation to the relevant factual and legal constraints that bear on the decision…" (*Vavilov* at para 99). The burden is on the party challenging the decision of demonstrate that it is unreasonable and the court must be satisfied that any shortcomings or flaws raised by that party are sufficiently central or significant to render the decision unreasonable (*Vavilov* at para 100).

[46] Issues of procedural fairness are to be reviewed on a correctness standard (*Mission Institution v Khela*, 2014 SCC 24 at para 79 and in *Canada (Citizenship and Immigration) v Khosa*, 2009 SCC 12 at para 43). In *Canadian Pacific Railway Company v Canada (Attorney General)*, 2018 FCA 69 [*CPR*], the Federal Court of Appeal held that the required reviewing exercise is best – albeit imperfectly – reflected in the correctness standard. The Court is to determine whether the proceedings were fair in all of the circumstances (*CPR* at paras 54-56; see also *Watson v Canadian Union of Public Employees*, 2023 FCA 48 at para 17).

Preliminary Issues

[47] The Attorney General of Canada raises two preliminary issues.

i. Style of Cause

[48] First, that the Attorney General of Canada is the only proper respondent to this application for judicial review. The Minister of Health is the decision-maker at issue and, therefore, should not be named as a respondent pursuant to Rule 303(1)(a) of the *Federal Courts Rules*, SOR/98-106.

[49] The Attorney General is correct (see for example *Canada (Attorney General) v Zalys*, 2020 FCA 81 at paras 1, 19-24). When appearing before me, counsel for Organigram confirmed that it takes no issue with the Attorney General's position. I will therefore order that the style of cause be amended to remove "Canada (Minister of Health)" as a named respondent in this application for judicial review.

ii. Affidavit Evidence

[50] The Attorney General submits that in an application for judicial review, the role of the Court is to consider whether the decision was reasonable. With limited exceptions for background information and procedural fairness, the only material that is relevant to a judicial review is that which was before the decision-maker (referencing *Tsleil-Waututh Nation v Canada (Attorney General)*, 2017 FCA 128 at paras 86, 98; *Association of Universities and Colleges of Canada v Canadian Copyright Licensing Agency (Access Copyright)*, 2012 FCA 22 at para 19 [*Assn of Universities & Colleges*]; *Delios v Canada (Attorney General)*, 2015 FCA 117 at paras 41-42 [*Delios*]).

[51] Accordingly, most of the affidavit of Ms. Beena Goldenberg, Chief Executive Officer of Organigram sworn on May 15, 2023 [Goldenberg Affidavit] and the affidavit of Mr. Jason Harquail, holding the position of Cannabinoid Science II at Organigram, sworn on May 15, 2023 [Harquail Affidavit] are irrelevant and of no value for considering the reasonableness of the Minister's decision, because they put forward information which was not before the Minister. This Court should only consider this affidavit evidence to the extent that it explains Organigram's procedural fairness arguments, and should otherwise look to what was before the Minister in the record.

[52] I agree with the Respondent that the law on this issue is clear. In *Assn of Universities & Colleges*, Justice Stratas pointed out that in determining the admissibility of an affidavit in support of an application for judicial review, the differing roles played by the Court and the

administrative decision-maker must be kept in mind (at para 14). Parliament gave the administrative decision-maker, and not the Court, jurisdiction to determine certain matters on their merits. Because of this demarcation of roles, the Court cannot allow itself to become a forum for fact-finding on the merits of the matter. Accordingly, as a general rule, the evidentiary record before a reviewing Court on judicial review is restricted to the evidentiary record that was before the decision-maker. Evidence that was not before the decision-maker and that goes to the merits of the matter is, with certain limited exceptions, not admissible (*Assn of Universities & Colleges* at paras 14-19).

[53] The recognized exceptions are an affidavit that: provides general background in circumstances where that information might assist the Court in understanding the issues relevant to the judicial review, but does not go further and provide evidence relevant to the merits of the matter decided by the administrative decision-maker; brings to the attention of the reviewing Court procedural defects that cannot be found in the evidentiary record of the administrative decision-maker so that the Court can fulfill its role of reviewing for procedural unfairness; or, highlights the complete absence of evidence before the administrative decision-maker when it made a particular finding (*Assn of Universities & Colleges* at para 20; see also *Bernard v Canada (Revenue Agency)*, 2015 FCA 263 at paras 19-25; and *Delios* at para 45).

[54] The Harquail Affidavit provides evidence as to the development of the Jolts lozenges that was not before Health Canada when it made its decision and attaches as exhibits literature, such as an article pertaining to the absorption of cannabinoids into the bloodstream, that was not before Health Canada. While Organigram argues that the Harquail Affidavit is highly relevant

background information necessary for the Court's understanding of the scientific issues, I do not agree. The material contained in the record clearly indicates Organigram's position that the Jolts were developed to be consumed via absorption under the tongue (sublingually) and/or through the skin of the cheek (buccally). New evidence as to science behind how those processes actually work is not necessary for the Court to understand the issues now before it. The Harquail Affidavit is mostly concerned with boot strapping Organigram's argument that the Jolts are not intended to be consumed in the same manner as food. The Harquail Affidavit evidence as to how the Jolts were developed could have been, but was not, before Health Canada and does not fall within the background exception.

[55] Therefore, beyond the limited portion of the Harquail Affidavit that arguably speaks to Organigram's assertion that it was denied procedural fairness, the Harquail Affidavit will be afforded no weight. Specifically, I will consider paragraph 19 of the affidavit as it is relevant to Organigram's submission that the decision took issue, for the first time, with the Jolts' shape and size as not fitting comfortably under the tongue or between the cheek and gum, as compared to other sublingual product formats.

[56] The Goldenberg Affidavit includes some general background information, which is also largely found within the CTR, and therefore is permissible. As stated in *Delios*, "the general background exception applies to non-argumentative orienting statements that assist the reviewing court in understanding the history and nature of the case that was before the administrative decision-maker… As long as the affidavit does not engage in spin or advocacy - that is the role of the memorandum of fact and law - it is admissible as an exception to the general rule" (at para

45; *Canadian Tire Corporation v Canadian Bicycle Manufacturers Association*, 2006 FCA 56 at paras 9-10; also see *Canada (Attorney General) v Quadrini*, 2010 FCA 47 at para 18).

[57] However, the Goldenberg Affidavit goes further and contains impermissible argument, including but not limited to an entire section devoted to why, in the affiant's view, Health Canada's reliance on public interest as a basis for its decision is misplaced, attaching six reports and articles as exhibits in support of this argument which were not before Health Canada. The affidavit also contains statements that are not supported by the record that was before Health Canada.

[58] To the extent that the Goldenberg Affidavit exceeds the bounds of the general background exception and is not concerned with Organigram's allegation of a breach of procedural fairness, I will afford it no weight (see *Foster Farms LLC v Canada (International Trade Diversification)*, 2020 FC 656 at para 40 [*Foster Farms*]).

Procedural Fairness

[59] Having reviewed and considered all of the parties' submissions, I have concluded that the issue of procedural fairness is determinative.

Content of procedural fairness

[60] The parties are in agreement as to the applicable law for assessing issues of procedural fairness, including the consideration of the *Baker* factors (*Baker v Canada (Citizenship and*

Immigration), [1999] 2 SCR 817 at paras 22-28 [*Baker*]) to determine the content of procedural fairness: the nature of the decision, the nature of the statutory scheme, the importance of the decision, legitimate expectations, and the procedural choice made by the decision-maker. They disagree, however, as to how the *Baker* factors apply in the specific context of this case.

Organigram's position

[61] Organigram submits that it was owed a substantial level of procedural fairness. It asserts that the nature of the decision was not administrative but was rather a specific determination for a business entity. It also notes the lack of appeal mechanism in the statutory scheme and asserts that the importance of the decision, given the consequence of having to remove "one of its most successful products from the market", favours a high level of procedural fairness. According to Organigram, it was therefore entitled to receive notice of the decision, to receive "complete disclosure of all information under consideration and which motivated Health Canada to issue" the Notice of Non-Compliance and the decision and, to be given a reasonable opportunity to respond to the evidence. When appearing before me, Organigram added that because, in its view, Health Canada changed its position on the Jolts' compliance with the *Cannabis Regulations*, this too called for a higher level of procedural fairness in consideration of the challenges for commercial investment and innovation in the cannabis industry.

Respondent's position

[62] The Respondent disagrees that Organigram was entitled to an elevated level of procedural fairness. The Respondent notes that the nature of the decision was regulatory, not adjudicative,

and despite the lack of an appeal mechanism in the statutory scheme, there is flexibility in the administration of the scheme. For example, Organigram was able to make further submissions in response to the Notice of Non-Compliance. The Respondent does not dispute that the decision has a commercial impact on Organigram but submits this does not reach the level of importance necessary for elevated procedural rights as contemplated by *Baker*, which generally concerns situations which have serious impacts on the lives of natural persons (at paras 25 and 31). Further, Organigram did not have any legitimate expectations to any specific procedure given that there is no published policy on the procedures to be followed by Health Canada when determining whether licence holders are non-compliant, given the novelty of the regime. The procedure whereby licence holders are provided with Health Canada's essential concerns, but not an exhaustive summary of every piece of evidence reviewed, given the number of cannabis products being regulated, is an "institutional constraint" that supported a lower level of procedural fairness (*Baker* at para 27).

Analysis

[63] I agree with the Respondent that Organigram was not entitled to an elevated level of procedural fairness and that, overall, the *Baker* factors point toward the lower end of the spectrum.

[64] There is no merit to Organigram's suggestion that the decision is not administrative in nature. As the Respondent points out, licence holders are regulated by Health Canada under the *Cannabis Act* and *Cannabis Regulations* regime. As such, they submit compliance information which Health Canada assesses. Further, the administrative process to be utilized in making

compliance decisions is not prescribed by the statutory regime. Such decisions are discretionary, involve the consideration of multiple factors and do not resemble judicial decision-making (*Baker* at paras 23, 31; *Foster Farms* at para 47). This, therefore, points to the lower end of the procedural fairness spectrum. While the lack of an appeal mechanism does point toward a higher duty owed, judicial review is available (*Baker* at paras 24, 31).

[65] As to the importance of the decision to the individuals affected, this Court has recently confirmed that commercial interests generally lie at the low end of the spectrum in terms of the importance of the decision (see: *Telus Communications Inc v Vidéotron Ltée*, 2022 FC 726 at para 91, citing *Airbus Helicopters Canada Limited v Canada (Attorney General)*, 2015 FC 257 at para 116). This factor cannot receive the same weight, in terms of the required level of procedural fairness, as situations where decisions affect the lives of individuals affected (*Foster Farms* at para 49).

[66] Further, there is nothing in the process or the provisions of the *Cannabis Act* or *Cannabis Regulations* that afforded Organigram a legitimate expectation that a certain procedure would be followed or result would be reached, despite the Organigram's interpretation of some of the correspondence. In that regard, there was no clear and convincing evidence supporting that an unqualified representation had been made, or that an established conduct or practice existed, such that it would have caused Organigram to have a legitimate expectation of any specific process for the making of the decision (*Foster Farms* at para 50). Finally, the *Act* afforded Health Canada the ability to choose its own procedures. This too points the content of procedural fairness owed to the lower end of the spectrum (*Baker* at para 27).

[67] In balancing the *Baker* factors in the circumstances of this matter, as indicated above, I find that the level of procedural fairness owed to Organigram falls at the lower end of the spectrum.

Whether the Minister provided adequate notice and disclosure

Organigram's position

[68] Organigram submits that Health Canada breached procedural fairness by failing to provide adequate notice and disclosure in the following respects:

1) The Notice of Non-Compliance failed to disclose underlying evidence (online reviews, social media posts (e.g. Reddit), and YouTube videos) that went into Health Canada's analysis, and two events that motivated Health Canada's compliance action: the Complaint and a serious adverse reaction report [SAR Report].

2) Health Canada introduced new arguments and issues in the decision by relying on the *Codex Alimentary General Standard for Food Additive*s [*Codex Standard*] and the *Labelling requirements for confectionary, chocolate and snack food products* [*Labelling Guide*] to support its finding that the Jolts are a food product.

3) Health Canada introduced a fourth factor in the decision that was omitted from the Notice of Non-Compliance and is not found in the *Guidance Document*: the product's sensory and physical characteristics. Organigram was not afforded an opportunity to respond to Health Canada's objection to the Jolts' size and shape or suitability for sublingual and buccal absorption.

4) Health Canada published a new guide for classifying products as cannabis extract or edible cannabis, the *Compliance promotion statement on the classification of edible cannabis* [*Compliance Promotion Statement*], just two days after the decision was issued. Organigram asserts that Health Canada withheld but relied upon this statement. Organigram therefore did not know the framework being relied upon by Health Canada when it made its submission on the proper classification of the Jolts.

[69] In light of all of the above, Organigram submits that Health Canada failed to disclose reliance on certain factors and information, yet relied on this evidence in rendering the decision while allowing Organigram to continue investing in the Jolts. Organigram asserts that this demonstrates a results-oriented analysis. It also emphasizes the importance of adequate notice, which is linked to a fair hearing, as a fair hearing requires the affected party to be informed of the case against them. Organigram agues that the substantive requirements of notice are only satisfied if the affected party "knows the essentials of the evidence" on the main issues to be determined. It also submits that it had the right to "verify and respond" to the evidence adduced against it (citing *Charkaoui v Canada (Citizenship and Immigration)*, 2007 SCC 9 at paras 53 and 88; *Mission Institution v Khela*, 2014 SCC 24 at para 88; *Kozul v Canada (Minister of Employment and Social Development)*, 2016 FC 1316 at paras 12-13). Organigram asserts that the undisclosed evidence was highly relevant in the decision and that its inability to respond to this material was prejudicial to its position.

Respondent's Position

[70] The Respondent submits that Organigram received an opportunity to respond to all of Health Canada's concerns raised in the Notice of Non-Compliance, which fairly sets out the relevant concerns. The Respondent disagrees that Health Canada withheld relevant evidence, noting that administrative decision-makers are not obligated to share every piece of information reviewed. Rather, the obligation is to let the party affected know the "essentials of the evidence" so they have a reasonable opportunity to respond (*Foster Farms* at para 53). The Respondent also notes that Rule 317 of the *Federal Courts Rules* requires tribunals to share "relevant" information to the application, and does not confirm that every document in the CTR is essential such that it ought to have been disclosed during the decision-making process.

[71] The Respondent argues that none of the evidence in question was in fact "essential" to the decision for the following reasons:

1) The social media posts, which included a Reddit comment referred to in the Preliminary Classification, while not provided to Organigram, were not relevant to the Notice of Non-Compliance or the decision, neither of which weighed public opinion to determine whether the product would be perceived as candy. The issue was the properties of and representations concerning the Jolts, which were the factors weighed by Health Canada. Health Canada's underlying concern that the Jolts are perceived as candy was directly put to Organigram in the Notice of Non-Compliance.

2) The YouTube video cited in the Second Classification, which was relied on in the decision, was only relied on for determining the size of the Jolts, and there was no obligation to disclose such minor or noncontroversial evidence.

3) The Respondent's written submissions argued that there is no evidence that the *Compliance Promotion Statement* was completed prior to the decision nor that Health Canada relied on it in making the decision. Nor did Organigram explain how this was an essential document for it to understand the case to be met. However, at the hearing before me, the Respondent acknowledged that a draft of the *Compliance Promotion Statement* existed and that in its decision Health Canada obviously used the headings from the *Compliance Promotion Statement.* Regardless, that the pertinent point to consider is that little turns on the use of the new heading, the content discussed by Health Canada under that heading had previously been raised with Organigram or was in response to Organigram's submissions.

4) While the Complaint initiated the process that let to the decision, it was irrelevant to the actual decision of whether the Jolts were properly classified as cannabis extract or edible cannabis. The Complaint itself was not "evidence" that received weight in the decision-making process. According to the Respondent, the central point of the Complaint was that, from a consumer perspective, the Jolts resemble hard candy, an issue that was put directly to Organigram.

[72] The Respondent also argues that the decision did not raise novel issues. The references to the *Codex Standard* and *Labelling Guide* were part of Health Canada's response to Organigram's argument against the Jolts being considered a confectionary product. The Respondent submits

that the *Codex Standard* and *Labelling Guide* references were used to reiterate Health Canada's interpretation of the *Guidance Document*. While the references were not in the Notice of Non-Compliance, the issue – how to interpret the *Guidance Document* – was. In a similar vein, the Respondent argues that the assessment of the Jolts' physical characteristics, shape and size, was in response to Organigram's position that the product instructions would cause consumers not to consume the Jolts as a candy. Health Canada noted, based on shape and size, that consumers may not follow the instructions – this was responsive to Organigram's submissions.

Analysis

[73] I am satisfied that a lower level of procedural fairness was owed to Organigram and that several opportunities to respond were provided to it throughout the decision-making process, with which Organigram engaged. However, when the all of the circumstances of the case are taken into account (*CPR* at para 54), I find that there was a breach of procedural fairness arising from inadequate notice of Health Canada's reliance on a factor contained in the *Compliance Promotion Statement* and, as a result, that Organigram was not afforded a meaningful opportunity to respond to that concern and thereby prejudiced in its ability to respond to that concern.

[74] That said, I do not agree with Organigram that Health Canada was obliged to disclose the social media post, YouTube video, the Complaint, SAR Report or the *Labelling Guide* and *Codex Standard*. Rather, I agree with the Respondent that these sources or materials were either irrelevant to the decision itself, were used to make uncontroverted findings, or, in responding to Organigram's submissions.

[75] First, the reference to the Reddit post is found only in the Preliminary Classification, not the Second Classification. When addressing public perception, the Preliminary Classification states that the Jolts are similar to candy and additionally "on social media sites such as Reddit, consumers reviewing the Jolts line of products have commented that they taste like a 'hard mint' which is a candy and have made comments on this product line being a 'workaround' of the edible cannabis THC limit". The Notice of Non-Compliance states that Health Canada's determination that the Jolts are consumed in the same manner as food is based on product representation, format and public perception or history of use, including that the products "may be perceived by consumers as intended for consumption in the same manner as both food products and cannabis edible". No reference is made to any documentation relied upon in support of the public perception finding. In its response, Organigram did address public perception but only in the context of the *Guidance Document*.

[76] Public perception is not a discrete factor addressed in the decision. Health Canada states only that the Jolts are in the format of confectionary products, specifically hard candies, and based on the *Guidance Document* it is their position that Canadians perceive and consume confectionary products as food. Such products also have a long history of being consumed as foods.

[77] Given that the Reddit post is not referenced in the Second Classification and that the reference to public perception in the decision is general in nature, I am not persuaded that Health Canada erred in failing to provide the post to Organigram.

[78] As to the other online sources, the Second Classification, under the heading "product sensory and physical characteristics", includes a photograph of the Jolts and attaches other various attributed photographs of the Jolts and their packaging and excerpts from two identified online reviews. The Second Classification states only that the Jolts are "spherical in shape, yellow, truculent and/or opaque and seem to have a rough to smooth texture," and, while there is no published information on the size of the Jolts, an online review qualifies them as "little" and shows pictures of them on top of the standardized cannabis symbol. A video shows them in comparison to a 25-cent coin. The Second Classification concludes that "[c]ontextually, the size of the lozenges can be inferred to be -1.0 cm in diameter". This is not information not known to Organigram who produces and packages the Jolts, nor does Organigram dispute the accuracy of the description. In these circumstances, Health Canada was not required to disclose the online sources it referenced to determine the size and shape of the Jolts.

[79] In Organigram's response to the Notice of Non-Compliance, under product representation and format, it referred to a portion of the *Guidance Document* which indicates that certain aspects of a product's label or associated advertising material may provide an indication that it is a natural health product (and not food): "For example, the use of the terms such as but not limited to 'lozenge', 'cough/throat drop' or 'cough tablets' supports classification as an NHP". Organigram asserted the Jolts are lozenges and are clearly represented as such.

[80] The decision found that the Jolts' format is consistent with hard candies which are confectionary products and a conventional food product in the *Guidance Document*. Additionally, the decision noted that the *Codex Standard* includes lozenges under the

confectionary food category as hard candy. The decision acknowledged Organigram's position that lozenges are commonly regulated as natural health products, and not food, but found that this classification was dependant upon the representation and composition of those products – not because they are in a food format – noting that a lozenge without any active ingredient or health claim would be regulated as hard candy. Health Canada stated that this finding was supported by the *Labelling Guide.*

[81] I agree with the Respondent that these references were used to reiterate Health Canada's interpretation of the *Guidance Document*. Organigram does not dispute that the Jolts' format is consistent with that of hard candies, or that hard candies are confectionary products. Its assertion was that because the Jolts are in "lozenge" format they should not be classified as food. In my view, the references to the *Codex Standard* and *Labelling Guide* simply further demonstrate Health Canada's point that that use the descriptor "lozenge" does not, in and of itself, establish that a product is not a confectionary product (and food). As nothing new arises from these references, I do not agree that Health Canada erred in failing to disclose those documents.

[82] As to the SAR Report, the Supplementary Certified Tribunal Record [Supplementary CTR] includes this incident but states that the report was not before the decision-maker when the decision was made. Further, the email pertaining to the SAR incident indicates that the incident arose from consumption of the Vortex Full Spectrum THC Jelly Cubes, not the Jolts. The Vortex product was taken by a consumer who was under the impression that the subject gummies were edibles having a THC limit of 10 mg per container, and consumed a number of gummies on that basis. She was taken to hospital where she was told she had overdosed on cannabis. Given that

the SAR Report was not before the Health Canada when the decision was made, that it does not concern the Jolts and is unrelated to a determination of whether Jolts are edible cannabis or cannabis extract, in my view Health Canada did not breach procedural fairness in failing to disclose it to Organigram.

[83] With respect to the Complaint, which was disclosed to Organigram after this application for judicial review was initiated, I acknowledge Organigram's observation that the analysis put forth in the Complaint is similar to Health Canada's analysis made in support of the decision. That said, I agree with the Respondent that the Complaint itself was not a factor considered by Health Canada in the decision as to whether the Jolts were properly classified as a cannabis extract or edible cannabis.

[84] However, I do agree with Organigram that Health Canada appears to have relied on the *Compliance Promotion Statement*, either directly or implicitly, in making the decision. It also appears that Health Canada may have relied on the *Classification Policy* in reaching the decision. Neither of these documents are referenced in the Notice of Non-Compliance.

[85] The specific concerns raised in the Notice of Non-Compliance are said to have been based on the classification factors of product representation, product format, and public perception or history of use. These are the three factors set out in the *Classification Policy* (which appears to be an internal Health Canada document). The *Classification Policy* is not referenced in the Notice of Non-Compliance, which refers only to *Guidance Document.* The

Guidance Document also includes product composition as a factor, which is not addressed as a discreet factor in the decision.

[86] The concerns as identified by Health Canada in the Notice of Non-Compliance were as follows:

> 1) The products have a likeness to confectionary-like products. The directions on the packages indicate that they are "Cannabis extract (lozenge) for ingestion".
>
> 2) The products are represented and marketed in a manner that highlights their taste and flavour. Cherry, lemon and mint are food flavours that are generally associated with confectionary products, or desserts.
>
> 3) Organigram Inc.'s Edison Jolts cannabis extract product line may be perceived by consumers as intended for consumption in the same manner as both food products and cannabis edibles. Confectionary products have a long history of being consumed as foods. This position is consistent with the *Guidance* for classifying food and natural health products.

[87] The *Compliance Promotion Statement*, attached as Exhibit Y to the Goldenberg Affidavit, adds a new, fourth factor which was assessed in the Second Classification and was considered in the decision: product sensory and physical characteristics. With respect to this factor, the *Compliance Promotion Statement* states:

> A cannabis product that has sensory or physical characteristics that the public perceives as food is another factor to be considered in

> the classification of edible cannabis. These include, but are not limited to:
>
> - taste and smell (for example, fruit flavoured)
>
> - appearance, texture, size, colour or shape similar to a food (for example, a gummy or hard candy)
>
> - composition (ingredients in the final product)

[88] The *Compliance Promotion Statement* was published by Health Canada two days after the decision was made. Its purpose is stated to include that Health Canada is aware of non-compliance regarding the classification of edible cannabis and is working with regulated parties to resolve the issue. A draft version of the statement is attached as Exhibit EE of the Goldenberg Affidavit.

[89] The fourth factor introduced by the *Compliance Promotion Statement,* "product sensory and physical characterises", appears for the first time in the Second Classification and subsequently in the decision, despite the *Compliance Promotion Statement* being published two days after the decision was rendered.

[90] The Notice of Non-Compliance did refer to the taste and flavour of the Jolts (cherry, lemon and mint), but did not explicitly indicate to Organigram that a potential issue could arise from the Jolts' appearance, colour, or shape, despite indicating that the products have a likeliness to confectionary products. While I agree that Organigram knew the overall concern about the Jolts potentially being considered as a product to be consumed in the same manner as food – that

is, a confectionary product, hard candy – the specific concerns arising from particular physical characteristics of the Jolts were not addressed in the Notice of Non-Compliance.

[91] The lack of disclosure of the *Compliance Promotion Statement*, in and of itself, may not have amounted to a breach of procedural fairness. However, the Second Classification and the decision suggest that, while not determinative, weight was placed on the observation that the Jolts resemble food, namely hard candy, due to their physical characteristics. The Second Classification recommendation drew particular attention to the fact that the "cannabis lozenges do not appear very different from cannabis drops or cannabis hard candies". Health Canada adopts this recommendation in the decision under the product sensory and physical characteristics heading when finding that the Jolts "appear to be a pale translucent yellow in colour and are spherical in shape. Their appearance does not have any distinguishing features from ordinary candy".

[92] Further, Health Canada's assessment of the fourth factor in the *Compliance Promotion Statement*, physical characteristics, also appears to have bled into its findings on product representation in the decision. Notably, Health Canada raises a new issue arising from the size and shape of the Jolts, and how these characteristics make them "not typical" to rest comfortably for absorption and "may cause individuals to not follow the instructions provided".

[93] The Respondent submits that Health Canada was entitled to express the view, based on its expertise, that the Jolts' size and shape would not fit comfortably under the tongue or between the cheek and gum until dissolved as compared to a sublingual format (such as sublingual drug

or natural health product tablets), which might cause individuals not to follow the instructions provided. However, in my view, the problem is that Health Canada did not alert Organigram to this concern and, therefore, it was not in a position to respond. I also do not agree that Health Canada's reference to physical characteristics – shape and size – was responsive to Organigram's contention that the product instructions would cause users not to consume Jolts as a candy. Organigram's position (under the product representation and format heading provided for in the *Guidance Document*) was that the directions for use were inconsistent with the consumption of food, in light of the *manner* of consumption (sublingual/buccal). Its position was not premised on the *suitability* of the Jolts size and shape for consumption in that manner. This was a new finding by Health Canada.

[94] I would also add that while Health Canada is to be afforded deference in its factual findings (see *Canadian Hardwood Plywood and Veneer Association v Canada (Attorney General)*, 2023 FCA 154, citing *Vavilov* at para 125), I found no evidence in the record before me to support its inference that the size and shape of the Jolts may cause consumers to not follow the instructions for use.

[95] In sum, in my view, the lack of notice and disclosure of Health Canada's concerns arising from the physical characteristics of the Jolts precluded Organigram from responding to concerns not previously raised in the Notice of Non-Compliance. The issues arising from the physical characteristics of the Jolts impacted two out of the four factors considered by Health Canada and were attributed weight in the Second Classification and the decision. In *Foster Farms*, relied on by the Respondent, Justice Gascon discussed the contextual requirements of procedural fairness.

In that case, the content of procedural fairness was similarly found to lie at the low end of the spectrum (para 56). With respect to notice, he stated that the object of notice is to ensure that the persons directly affected by a pending decision are "provided with *sufficient* information and opportunities to meet the case" against them (para 59). As to the sufficiency of notice, Justice Gascon stated:

> [60] The notice requirement dictates that applicants be provided with the information necessary to build and present their best case to a decision maker, taking into account the factors that are likely to be considered and the process involved. Such notice requirement does not extend to draft decisions or memoranda written to inform a decision maker. Unless new and relevant information comes to the decision maker's attention that would influence the disposition, there is no requirement to go back to the applicant for further commentary (*Uniboard Surfaces Inc v Kronotex Fussboden GmbH and Co KG*, 2006 FCA 398 [*Uniboard*] at paras 21-22; *Canadian Cable Television Assn v American College Sports Collective of Canada Inc*, 1991 CanLII 13580 (FCA), [1991] 3 FC 626 at paras 31-37).
>
> [Emphasis added]

[96] Here, given the process affected by Health Canada – the utilization of a Notice of Non-Compliance and affording Organigram the opportunity to respond to the matters raised in that notice – the subsequent introduction of the fourth factor found in the *Compliance Promotion Statement* (or a draft version of that statement) constituted such "new and relevant information" that influenced the disposition of the decision. Accordingly, I find that Organigram was not provided with adequate notice of the fourth factor contained in the *Compliance Promotion Statement*, which was relied upon by Health Canada in making its decision. As a result, Organigram was not afforded a meaningful opportunity to respond to that concern.

[97] For these reasons, I also reject the Respondent's argument, in the alternative, that even if there was a breach of procedural fairness, the issues were minor and would not have affected the outcome of the decision and that accordingly, the decision should stand.

[98] Breaches of procedural fairness will ordinarily render a decision invalid, and the usual remedy is to order a new hearing (*Cardinal v. Director of Kent Institution*, 1985 CanLII 23 (SCC), [1985] 2 S.C.R. 643, [1985] S.C.J. No. 78 (QL)). Exceptions to this rule exist where the outcome is legally inevitable (*Mobil Oil Canada Ltd. v. Canada-Newfoundland Offshore Petroleum Board*, 1994 CanLII 114 (SCC), [1994] 1 S.C.R. 202 at pp. 227-228; 1994 CarswellNfld 211 at paras 51-54).

[99] This was recently restated by the Federal Court of Appeal in *Canada v Bowker*, 2023 FCA 133 [*Bowker*]:

> [77] A finding of breach of procedural fairness renders a decision liable to be overturned: *Cardinal v. Kent Institution*, 1985 CanLII 23 (SCC), [1985] 2 S.C.R. 643 at para. 23, *Université du Québec à Trois-Rivières v. Larocque*, 1993 CanLII 162 (SCC), [1993] 1 S.C.R. 471 at 493. However, a court may exercise its discretion to not grant a remedy for breach of procedural fairness where the result is inevitable: *Mobil Oil Canada Ltd. v. Canada-Newfoundland Offshore Petroleum Board*, 1994 CanLII 114 (SCC), [1994] 1 S.C.R. 202 at 228-229, *Rebello v. Canada (Justice)*, 2023 FCA 67 at para. 16.

[100] I am not persuaded that the result was inevitable in this case. Health Canada's assessment of the fourth factor of the *Compliance Promotion Statement* appears to have played a not insignificant role in its decision and in the weighing process conducted in the underlying Second Classification. If or how that weighing exercise may be conducted differently upon consideration

of a response to this concern from Organigram cannot be determined by this Court. Thus, while Health Canada's decision may otherwise have been reasonable, the breach of procedural fairness requires that it be redetermined.

[101] Before concluding, I would observe that the process by which Health Canada assesses the classification of products, as submitted by producers, as either edible cannabis or cannabis extract, is relatively new and appears to have been in transition during the time leading up to the making of the decision. For example, the *Preliminary Classification* indicates that it was based on the *Classification Policy* – an internal document which is specifically concerned with the classification of ingestible cannabis products and is dated September 8, 2022. However, the Second Classification and the decision make no reference to the *Classification Policy* (possibly because it is an internal document) and instead explicitly refers only to the 2017 *Guidance Document*, which concerns the classification of products at the natural health products interface, not cannabis. Meanwhile, the *Compliance Promotion Statement* was clearly under development and, as discussed above, was indirectly referred to in the Second Classification and the decision. All of which is to say, in an effort to avoid future challenges based on procedural fairness, Health Canada should consider clearly identifying the policy(s) and procedures upon which it will rely in making determinations of non-compliance based on the classification of cannabis products and inform concerned parties concerned accordingly.

Conclusion

[102] Given my finding that Health Canada breached the duty of procedural fairness by relying on a product classification factor found only in the *Compliance Promotion Statement*, which was

published after the decision was issued, I need not address Organigram's further procedural fairness submission based on delay, nor the submissions as to the reasonableness of the decision.

[103] The matter must be remitted back to Health Canada for redetermination, taking these reasons into consideration.

Costs

[104] When appearing before me, the parties advised that they had agreed on the all-inclusive sum of $5000 for costs in the cause.

JUDGMENT IN T-651-23

THIS COURT'S JUDGMENT is that

1. The application for judicial review is granted;
2. The matter will be remitted back to Health Canada for redetermination taking these reasons into consideration;
3. The style of cause is hereby amended removing "Canada (Minister of Health)" as a named respondent; and
4. Organigram shall have its costs in the all-inclusive lump sum amount of $5000.

"Cecily Y. Strickland"
Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-651-23
STYLE OF CAUSE:	ORGANIGRAM INC v ATTORNEY GENERAL OF CANADA
PLACE OF HEARING:	BY VIDEOCONFERENCE USING ZOOM
DATE OF HEARING:	JULY 25, 2023
JUDGMENT AND REASONS:	STRICKLAND J.
DATED:	AUGUST 8, 2023

APPEARANCES:

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